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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,501	09/26/2003	Ryszard Kole	5470-378	3535

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EXAMINER	
HORLICK, KENNETH R	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/672,501	KOLE, RYSZARD	
	Examiner	Art Unit	
	Kenneth R. Horlick	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 26 September 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/17/04;5/5/04 (4 pages)
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is confusing because "the splicing machinery" lacks proper antecedent basis. This claim is further confusing because of missing essential subject matter: while there is a second step of "detecting expression of the cDNA to produce a gene product", the claim fails to recite an essential step wherein the cDNA supplied in the first "contacting" step is expressed to produce a gene product, such that said product can be detected. Still further, this claim is confusing because the preamble and final step recite "modulating a splicing event in a pre-mRNA molecule", but the first step mentions a "cDNA" without any relation to said pre-mRNA. Correction is required.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Each of these claims requires the use of a "compound identified according to the method of claim 1". Claims such as this, which require the use of hypothetical compounds not described at the time of the invention,

but which might be discovered at some future time, are sometimes referred to as "reach-through" claims in Technology Center 1600. As such hypothetical compounds are completely lacking in any physical, chemical, or structural properties, there is no basis for searching the prior art, and clearly applicant was not in possession of any such compounds, let alone pharmaceutical compositions comprising such compounds or methods of using such compounds. Thus, the claims clearly fail to satisfy the written description requirement.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by WO 01/79853.

This claim is drawn to a method comprising: contacting a compound with a spliceable cDNA and splicing elements, and detecting expression of any gene product expressed from properly-spliced cDNA.

While the cited document is not in the English language, the English title and abstract clearly disclose the claimed method.

4. The following is a quotation of 35 U.S.C: 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chabot et al. (US 2004/0048376).

The subject matter of claim 1 is described above.

Chabot et al. disclose a method of identifying compounds that modulate splicing reactions, comprising contacting a splicing reaction mix containing a spliceable nucleic acid with a candidate compound and analyzing the mix for splicing products. In determining modulation of splicing, either the spliced RNA unit or the protein encoded thereby (i.e., the expressed gene product) is monitored (see paragraphs 0016 and 0038).

Chabot et al. do not explicitly disclose using a cDNA as the spliceable nucleic acid (pre-mRNA is taught). However, in paragraph 0062, this document refers to cDNA as among the forms of nucleic acid which were conventionally used in the art for various purposes.

One of ordinary skill in the art would have been motivated to modify the method of Chabot et al. by using a cDNA as the spliceable nucleic acid because cDNA was conventionally used in the art, was well known in the art to be more stable than RNA, and was well known in the art for use in cloning and expression of gene products (this is merely textbook knowledge). Thus the benefits of replacing the pre-mRNA spliceable

nucleic acid of Chabot et al. with a cDNA equivalent would have been readily apparent to the skilled artisan. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed method.

5. It is noted that WO 00/67580 is close prior art, but also fails to teach use of cDNA as a spliceable nucleic acid, and additionally does not teach detection of polypeptide or protein expression products as opposed to RNA splicing products.

6. No claims are allowable.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R. Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kenneth R. Horlick Ph.D.

Kenneth R Horlick
Primary Examiner
Art Unit 1637

12/20/05